K 131546

BECKMAN COULTER

510k Summary
AU Bicarbonate Reagent

1.0 Submitted By:

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OCT 0 9 2013

2.0 Date Submitted:

April 24, 2013

3.0 Device Name(s):

3.1 Proprietary Names
AU Bicarbonate Reagent

3.2 Classification Name
Bicarbonate/carbon dioxide test system (21 CFR § 862.1160)

4.0 Predicate Device:

Candidate(s)	Predicate	Manufacturer	Docket Number
AU Bicarbonate Reagent	Carbon Dioxide - DST	Trace	K960035

5.0 Description:

The AU Bicarbonate reagent kit is a liquid, ready to use and consists of four R1 reagent vials in various fill volumes. The calibrator is a Beckman Coulter lyophilized chemistry calibrator packaged as catalog number DR0070 and sold separately. The AU Bicarbonate reagent is an enzymatic method utilizing Bicarbonate (HCO_3^-) and phosphoenolpyruvate (PEP), which are converted to oxaloacetate to malate with the concomitant oxidation of reduced nicotinamide adenine dinucleotide (NADH). This oxidation of NADH results in a decrease in absorbance of the reaction mixture measured bichromatically at 380/410nm proportional to the Bicarbonate content of the sample.
The AU Bicarbonate reagent is designed for optimal performance on Beckman Coulter AU analyzers.

6.0 Intended Use:

AU Bicarbonate reagent is intended for the quantitative determination of Bicarbonate in human serum and plasma on Beckman Coulter AU analyzers.

Bicarbonate measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

For *in vitro* diagnostic use.

Clinical Significance

Bicarbonate measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

7.0 Comparison to Predicate(s):

The following tables shows similarities and differences between the predicate identified in Section 4.0 of this summary.

Similarities		
Feature	AU Bicarbonate Reagent	Predicate
Intended Use	System reagent for the quantitative determination of Bicarbonate in human serum and plasma on Beckman Coulter AU analyzers.	Similar This reagent is intended for in vitro quantitative determination of total carbon dioxide in human serum on both automated and manual systems.
Measurement	Quantitative	Same
Reagent	Liquid, Ready for use	Same
Assay Methodology/Operating Principle	Enzymatic Photometric	Same
Calibration	Serum based calibrator traceable to NIST standard (Cat #DR0070)	Similar Recommended to use an aqueous or serum based calibrator traceable to a primary standard (e.g. NIST or IRMM)
Linearity Range	2.0 - 45.0 mEq/L	Similar 3 - 50 mEq/L
Expected Values	23 - 29 mEq/L	Same 23.0 - 29.0 mEq/L

Differences		
Feature	AU Bicarbonate Reagent	Predicate
Instrumentation	Beckman Coulter AU Analyzers	Automated and manual systems
Specimen Type	Serum and Plasma (Sodium Heparin and Lithium Heparin)	Serum
Reagent On Board Stability	Opened reagents are stable for seven days when stored in the refrigerated compartment of the analyzer	Not specified
Calibration Frequency	Daily	Not specified
Sensitivity	LoB = 1.20 mEq/L LoD = 1.95 mEq/L	Analytical 0.01 ΔA per mEq/L
Interfering Substances	Unconjugated Bilirubin: No significant interference up to 40 mg/dL Conjugated Bilirubin: No significant interference up to 20 mg/dL Hemolysis: No significant interference up to 500 mg/dL Lipemia: No significant interference up to 1000 mg/dL Intralipid No significant interference is recovery within 10% of initial value	Unconjugated Bilirubin: No interference up to 18.6 mg/dL Conjugated Bilirubin: No interference up to 18.7 mg/dL Haemoglobin: No interference up to 520 mg/dL Lipemia: No interference measured at absorbance 630 nm, up to 1.77 AU

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to a predicate chemistry test systems already in commercial distribution. Equivalence is demonstrated through performance characteristics testing. Experiments included: Method Comparison, Precision, Linearity, Sensitivity, Interferences, Stability and Expected Values, as outlined in FDA's guidance entitled "*In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System.*"

Performance on method comparison and precision are summarized below:

Method Comparison Study Results

Reference	Test	Sample Range:	Specifications	Results	Pass/ Fail
Thermo Scientific (TR28321)	AU Bicarbonate (OSR6x37)	Ref: 5.63 mEq/L - 45.44 mEq/L Test: 4.69 mEq/L - 41.85 mEq/L	Slope: 0.900-1.100	Slope: 0.922	Pass
			Intercept: ±2.0mEq/L	Intercept: 1.148mEq/L	Pass
			r: ≥ 0.95	r: 0.9909	Pass
			N: >100	N: 133	Pass

Precision Study Results

Sample	Concentration mEq/L	Within run precision			Total precision			Pass/ Fail
		%CV	SD	Specification	%CV	SD	Specification	
Low pool	12.3	2.5	0.30	≤3%CV or SD≤1	7.5	0.92	≤7%CV or SD ≤1.5mEq/L	Pass
Med pool	31.0	1.1	0.35	≤3%CV or SD≤1	4.0	1.23	≤7%CV or SD ≤1.5mEq/L	Pass
High pool	40.3	0.8	0.34	≤3%CV or SD≤1	3.6	1.47	≤7%CV or SD ≤1.5mEq/L	Pass

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 9, 2013

Beckman Coulter Ireland, Inc.
c/o David G. Davis
250 S. Kraemer Blvd.
BREA CA 92821

Re: K131546
Trade/Device Name: AU Bicarbonate Reagent
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: II
Product Code: KHS
Dated: August 21, 2013
Received: August 29, 2013

Dear Mr. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k131546

Device Name: AU Bicarbonate Reagent

Indications for Use: AU Bicarbonate reagent is intended for the quantitative determination of Bicarbonate in human serum and plasma on Beckman Coulter AU analyzers.

Bicarbonate measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

For In Vitro Diagnostic Use

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)___k131546_____